510(k) Summary

Pursuant to 21CFR807.92(c), Quest Medical Inc. provides the following Summary for this Premarket Notification.

OCT 19 2012

A. Submitter Information

Quest Medical, Inc.
One Allentown Parkway
Allen, TX 75002 USA
972-390-9800 / 800-627-0226; Fax 972-390-2881
Amy Clendening-Wheeler
October 18, 2012

B. Device Information

Trade/Device name: LacriCATH® Lacrimal Duct Balloon Catheter
Product Code: OKS
Device Classification Name: Lacrimal Stents and Intubation Stents
Regulatory Class: Unclassified

C. Legally Marketed Predicate Device

Iolab Lacrimal Duct Catheter, K935233

D. Device Description

The Quest Medical, Inc. current legally marketed LacriCATH lacrimal duct catheters are sterile, hand held, ophthalmic surgical devices. The LacriCATH devices are designed to facilitate nasolacrimal duct surgeries by using balloon dilation to open occluded lacrimal passages. Each LacriCATH catheter has a stainless steel tube with positioning markers and an inflatable balloon. A luer connector on the proximal end of the catheter is attached to a separate inflation device or a syringe for inflation and deflation of the balloon. The balloon is designed to inflate to a known diameter and length at the specified pressure. The LacriCATH lacrimal duct catheters are sterile, single-use, biocompatible medical devices that are sterilized by ethylene oxide and labeled with a 3 year shelf life. The LacriCATH catheters are packaged with 1 device per pouch, and 2 pouches per carton. They are available by prescription only.

E. Intended Use/Indications for Use

The intended use and the Indications for use for the new LacriCATH model numbers are the same as for the predicate devices. Compared to the labeling for the predicate device, the modified labeling contains the same information but organized to be clearer to the intended user. There is no impact to the use of the device or the safety and effectiveness of the device.

Intended Use Statement:

The LacriCATH Lacrimal Duct Balloon Catheter is a sterile, prescription device intended for single use during dilatation of an obstructed nasolacrimal duct system to correct epiphora.

Indications for Use Statement:

The LacriCATH Lacrimal Duct Balloon Catheter is a sterile, prescription device intended for single use during dilatation of an obstructed nasolacrimal duct system to correct epiphora as a result of the following:

5 mm - LacriCATH Adult Catheter:
Functional or complete nasolacrimal duct obstruction
Dacryocystitis
Failed DCR (Dacryocystorhinostomy)

2mm/3mm LacriCATH Pediatric catheter (intended for patients 12 months of age and older):
Congenital nasolacrimal duct obstruction
Dacryocystocele

F. Technological Characteristics:

The new LacriCATH catheters have the same technological characteristics compared to the predicate device. They have the same design and mode of operation. Only the length of the catheter has been modified, and the materials for the balloon, strain relief, and adhesive were updated. The sterilization method has been updated and the shelf life extended to 3 years. Table 1 below provides a comparison of the new LacriCATH catheters to the predicate device. This table illustrates equivalency of the LacriCATH catheters with the predicate device.

TABLE 1

	Predicate Device	**Modified Device**
510(k)	K935233	Under Review
Brand Name	Lacrimal Duct Catheter	LacriCATH® Lacrimal Duct Catheter
Model #	LDC213, LDC315, LDC508	LDC213T, LDC315T, LDC508T,
Manufacturer	Iolab originally, then Quest Medical, Inc.	Quest Medical, Inc
Materials		
Balloon, Outer tubing	LDPE – low density Polyethylene	Nylon balloon No outer tubing
Sheath/Sleeve	Teflon	**SAME**
Catheter	304 stainless Steel	**SAME**
Adhesive	Loctite™ 4541 – medical grade cyanoacrylate	Dymax 203A-CTH-F medical grade adhesive

	Predicate Device		Modified Device
Luer Connector	Polycarbonate		**SAME**
Strain Relief	Polyether polyamide polymer		Onflex TPE
Material: Markers	Medical Grade Ink - Black		**SAME**
Dimensions			
Balloon Size	2 mm diameter / 13 mm length- 3 mm diameter/ 15 mm length 5 mm diameter/ 8 mm length		**SAME**
Balloon Diameter	Deflated: 0.8 mm Inflated: 2 mm 0.9 mm 3 mm 1.1 mm 5 mm		**SAME**
Catheter Length	245 mm		200 mm
Sterilization/Pkg			
Method	Gamma radiation		Ethylene Oxide (EtO)
Minimum SAL	1×10^{-6}		**SAME**
Packaging	Tyvek polyethylene/Mylar pouch; heat-sealed		**SAME**
Shelf Life	Original: Indefinite as long as package integrity is not compromised	Quest: 3 years	3 years

G. Non-clinical Performance Data:

Preclinical (bench) testing completed for the modified LacriCATH catheters included mechanical/functional testing, biocompatibility, physicochemical testing, shelf life testing, and sterilization residuals testing. There was no additional testing required as a result of the Risk Assessments performed for the modification for the new LacriCATH catheters. Verification and Validation tests were performed to ensure the modified LacriCATH catheters continued to meet or exceed specification in accordance to the Design Requirements. Those specifications are the same as for the predicate device. There were no clinical tests performed. The bench-testing concluded that the new modified LacriCATH catheters performed as well or better than the predicate device. Testing for the new LacriCATH Model numbers demonstrates they are as safe and as effective as the predicate device.

H. Clinical Testing

None required.

I. Conclusions

Based on the information presented in this 510(k) premarket notification, the Quest Medical LacriCATH lacrimal duct catheters is considered substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 19 2012

Quest Medical, Inc.
c/o Amy Clendening-Wheeler
Sr. Regulatory Affairs Specialist
One Allentown Parkway
Allen, TX 75002

Re: K113867
Trade/Device Name: LacriCATH® Lacrimal Duct Balloon Catheter
Regulation Number: None
Regulation Name: Lacrimal Stents and Intubation Sets
Regulatory Class: Unclassified
Product Code: OKS
Dated: October 11, 2012
Received: October 12, 2012

Dear Ms. Clendening-Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah Falls

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113867

Device Name: LacriCATH® Lacrimal Duct Balloon Catheters

Indications for Use: The LacriCATH Lacrimal Duct Balloon Catheter is a sterile, prescription device indicated for single-use during dilatation of an obstructed nasolacrimal duct to correct epiphora as a result of the following:

5mm LacriCATH Adult catheter:
- functional or complete nasolacrimal duct obstruction
- dacryocystitis
- failed DCR (dacryocystorhinostomy)

2mm/3mm LacriCATH Pediatric catheter (intended for patients 12 months of age and older):
- congenital nasolacrimal duct obstruction
- dacryocystocele

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K113867